

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 14875-0155US1	Application No. 10/564,665
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant Reiko Irie et al.		
		Filing Date September 21, 2006	Group Art Unit 1644	

<b>U.S. Patent Documents</b>							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1	2004/0170623	09/02/2004	Tudor et al.			
	2	2005/0118167	06/02/2005	Akira et al.			
	3	2006/0127395	06/15/2006	Tudor et al.			
	4	2007/0249812	10/25/2007	Hayasaka et al.			
	5	2007/0212346	09/13/2007	Igawa et al.			
	6	5,157,113	10/20/1992	Dove et al.			
	7	5,190,752	03/02/1993	Möller et al.			
	8	5,792,838	08/11/1998	Smith et al.			
	9	5,908,826	06/01/1999	Fukuda et al.			
	10	6,136,312	10/24/2000	Rentsch			
	11	6,238,891	5/29/2001	Maioresca et al.			

<b>Foreign Patent Documents or Published Foreign Patent Applications</b>							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
							Yes      No
	12	EP 0 352 500	01/31/1990	Europe			Abstract only
	13	EP 1 174 148	01/23/2002	Europe			
	14	JP 2-000493	01/05/1990	Japan			Abstract only
	15	JP 2-078635	03/19/1990	Japan			Abstract only
	16	JP 6-189781	07/12/1994	Japan			Abstract only
	17	JP 7-502497	03/16/1995	Japan			Abstract only
	18	JP 9-127112	05/16/1997	Japan			Abstract only
	19	JP 9-127114	05/16/1997	Japan			Abstract only
	20	JP 2001-504092	03/27/2001	Japan			Abstract only
	21	WO 89/04867	06/01/1989	WIPO			
	22	WO 91/18106	11/28/1991	WIPO			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 14875-0155US1	Application No. 10/564,665
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant Reiko Irie et al.		
		Filing Date September 21, 2006	Group Art Unit 1644	

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	23	WO 93/08837	05/13/1993	WIPO				
	24	WO 99/37329	07/29/1999	WIPO				
	25	WO 00/66160	11/09/2000	WIPO			English abstract	
	26	WO 02/096457	12/05/2002	WIPO				
	27	WO 2005/035573	04/21/2005	WIPO			English abstract	
	28	WO 2005/035574	04/21/2005	WIPO			English abstract	

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	29	CHEN et al.. "Strategies to Suppress Aggregation of Recombinant Keratinocyte Growth Factor During Liquid Formulation Development," <i>J. Pharm. Sci.</i> , 83:1657-1661 (1994)
	30	DRÁBER et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose," <i>Journal of Immunological Methods</i> , 181:37-43 (1995)
	31	GARCÍA-GONZÁLEZ et al., "Purification of Murine IgG3 and IgM Monoclonal Antibodies by Euglobulin Precipitation," <i>Journal of Immunological Methods</i> , 111:17-23 (1988)
	32	GOMBOTZ et al., "The Stabilization of a Human IgM Monoclonal Antibody with Poly(vinylpyrrolidone)," <i>Pharm. Res.</i> 11:624-632 (1994)
	33	KALLEMUCHIKKAL et al., "Evaluation of cryoglobulins," <i>Arch. Pathol. Lab. Med.</i> , 123:119-125 (1999)
	34	MIDDAUGH et al., "Effect of solutes on the cold-induced insolubility of monoclonal cryoimmunoglobulins," <i>J. Biol. Chem.</i> , 252:8002-06 (1977)
	35	MIDDAUGH et al., "Molecular basis for the temperature-dependent insolubility of cryoglobulins. IV. Structural studies of the IgM monoclonal cryoglobulin McE," <i>Immunochem.</i> , 15:171-187 (1978)
	36	MOLINA et al., "The Effects of Divalent Cations in the Presence of Phosphate, Citrate and Chloride on the Aggregation of Soy Protein Isolate," <i>Food Research International</i> , 32:135-143 (1999)
	37	MONICA et al., "Comparative Biochemical Characterization of a Human IgM Produced in Both Ascites and <i>In vitro</i> Cell Culture," <i>Biotechnology</i> , 4:512-515 (1993)
	38	NIFONG et al., "Separation of IgG and IgM from albumin in citrated human plasma using electrodialysis and metal ion affinity precipitation," <i>ASAIO J.</i> , 48:645-649 (2002)
	39	PAGE et al., "Purification of monoclonal antibodies," <i>Methods Mol. Biol.</i> , 80:113-119 (1998)
	40	PHILLIPS et al., "Manufacture and quality control of CAMPATH-1 antibodies for clinical trials," <i>Cytotherapy</i> , 3:233-242 (2001)
	41	SHARMA et al., "Study of IgM Aggregation in Serum of Patients with Macroglobulinemia," <i>Clin. Chem. Lab. Med.</i> , 38:759-764 (2000)
	42	STEINBUCH et al., "Preparation of an IgM and IgA enriched fraction for clinical use," <i>Prep. Biochem.</i> , 3:363-373 (1973)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 14875-0155US1	Application No. 10/564,665
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant Reiko Irie et al.	
		Filing Date September 21, 2006	Group Art Unit 1644

<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>		
Examiner Initial	Desig. ID	Document
	43	U.S. EXAMINER AGNES BEATA ROOKE, USPTO Non-Final Office Action in U.S. App. Ser. No. 10/574,827, dated March 12, 2008, 11 pages
	44	FISH & RICHARDSON P.C., Amendment in Reply to Action dated March 12, 2008 in U.S. App. Ser. No. 10/574,827, filed September 11, 2008, 9 pages
	45	U.S. EXAMINER CHIH MIN KAM, USPTO Non-Final Office Action in U.S. App. Ser. No. 10/574,827, dated December 19, 2008, 7 pages
	46	FISH & RICHARDSON P.C., Amendment in Reply to Action dated December 19, 2008 in U.S. App. Ser. No. 10/574,827, filed June 18, 2009, 5 pages
	47	JAPANESE PATENT OFFICE, International Search Report for App. Ser. No. PCT/JP2004/014919, mailed December 7, 2004, 4 pages
	48	JAPANESE PATENT OFFICE, International Preliminary Report on Patentability for App. Ser. No. PCT/JP2004/014919, dated September 12, 2005, 14 pages
	49	U.S. EXAMINER SHARON X. WEN, USPTO Restriction Requirement in U.S. App. Ser. No. 10/575,192, dated April 15, 2008, 7 pages
	50	FISH & RICHARDSON P.C., Response to Restriction Requirement dated April 15, 2008 in U.S. App. Ser. No. 10/575,192, filed September 12, 2008, 1 page
	51	U.S. EXAMINER SHARON . WEN, USPTO Non-Final Office Action in U.S. App. Ser. No. 10/575,192, dated January 26, 2009, 11 pages
	52	JAPANESE PATENT OFFICE, International Search Report for App. Ser. No. PCT/JP2004/014935, mailed January 25, 2005, 4 pages
	53	JAPANESE PATENT OFFICE, International Preliminary Report on Patentability for App. Ser. No. PCT/JP2004/014935, 14 pages
	54	EUROPEAN EXAMINER PETER BUMB, European Search Report for App. Ser. No. EP 04 79 2204, mailed July 11, 2007, 3 pages
	55	JAPANESE PATENT OFFICE, International Search Report for App. Ser. No. PCT/JP2004/010444, mailed October 26, 2004, 4 pages
	56	JAPANESE PATENT OFFICE, International Preliminary Report on Patentability for App. Ser. No. PCT/JP2004/010444, dated June 3, 2005, 5 pages

Examiner Signature  /Ilia Ouspenski/	Date Considered  11/30/2009
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	